THE STATE INSTITUTE FOR DRUG CONTROL
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RECIPIENT
arex PHARMA

DELIVERY ADDRESS
K sokolovně 218
Prague 10 - Uhříněves
104 00

File No. sukls92265/2024
Ref. no.: sukl142638/2024

Contact person/extension
Mgr. Kateřina Gottvaldová / 420

Date 10 June 2024

Sent on the date of posting indicated by the post office on the envelope, on the date of sending a data message from the data box of the State Institute for Drug Control, or on the date of delivery to the addressee in the case of personal delivery to the addressee.

DECISION

The State Institute for Drug Control with registered office in Prague 10, Šrobárova 48, as an authority competent to decide in accordance with Section 13 (2)(a)(2) of Act No. 378/2007 Sb., on Pharmaceuticals and on Amendment to Some Related Acts (the Act on Pharmaceuticals), as amended, decided in compliance with the provisions of Section 67 of Act No. 500/2004 Sb., the Rules of Administrative Procedure, as amended (hereinafter "the Rules of Administrative Procedure")

a s f o l l o w s :

In accordance with Sections 76 and 63 (1) of Act No. 378/2007 Sb., on Pharmaceuticals and on Amendment to Some Related Acts (the Act on Pharmaceuticals), as amended (hereinafter "the Act on Pharmaceuticals"), as requested by arex PHARMA s.r.o. with registered office at K sokolovně 218, Uhříněves, 104 00 Prague 10, Company ID 015 02 565, the State Institute for Drug Control

changes the decision on authorisation for distribution of medicinal products
issued under the File No. sukls95568/2013 on 17 September 2013 as follows:

1. The scope of distribution activities shall be extended by the distribution of medicinal substances and excipients to persons authorised to prepare medicinal products.

2. The scope of the drug distribution authorisation specified in Annex No. 1 shall be extended by point 1.2 (distribution of medicinal products without marketing authorisation in the EEA and designated for the EEA's market and point 1.3 (distribution of medicinal products without marketing authorisation in the EEA and designated for export).

3. Individual distribution points (approved storage premises) and the scope of distribution are listed in Annex No. 1.

4. The inspection that led to the issuance of the decision to change the authorisation for distribution had been conducted on 18 April 2024.

The information contained in this Decision and its Annexes corresponds to the document entitled Compilation of Community Procedures on Inspection and Exchange of Information, as amended as of 2 January 2013.

R e a s o n i n g

On 12 March 2024, arex PHARMA s.r.o. with registered office at K sokolovně 218, Uhříněves, 104 00 Prague 10, Company ID 015 02 565, filed an application to change the authorisation for distribution of medicinal products. By filing the application, the administrative procedure registered under File No. sukls92265/2024 was commenced. Under this procedure and on the basis of results of the inspection conducted in situ on 18 April 2024, the State Institute for Drug Control (hereinafter the Institute) considered whether the requirements given by the Act of Pharmaceuticals, its implementing regulations and special regulations have been met in this case. Having completed the procedure, the Institute establishes that the application can be granted, and therefore decides to change the authorisation for distribution of medicinal products, as specified in the statement of this decision.

Following the legal force of the decision to change the authorisation for distribution of medicinal products, the authorisation for distribution of medicinal products granted to arex PHARMA s.r.o. with registered office at Býšť 78, 533 22 Býšť, Company ID 015 02 565, under File No.: sukls95568/2013 dated 17 September 2013, changed by the decision on change made under File No. sukls101548/2015 dated 5 August 2015, File No.: sukls197224/2015 dated 9 November 2015, File No. sukls34371/2016 dated 5 February 2016, File No. sukls79380/2017 dated 29 May 2017, File No. sukls291316/2021 dated 4 January 2022, File No. sukls14045/2023 dated 14 February 2023 and File No. sukls55451/2024 dated 12 March 2024, shall be in the following scope:

First name and surname of the natural person / corporate name or name of the legal entity	arex PHARMA s.r.o.
Place of business/registered office	K sokolovně 218, Uhříněves, 104 00 Prague 10
Company ID	015 02 565
Scope of operations	Distribution of medicinal products Distribution of medicinal substances and excipients to persons authorised to prepare medicinal products
Addresses of warehouses and names of qualified persons	K Sokolovně 218, 104 00 Prague 10 – Uhříněves (3 rooms on the 2nd floor, total area of 558 m^2) MVDr. Vít Pajurek, Ing. Jindra Lekešová
Addresses of contractual distribution points and names of qualified persons	---

N o t i c e o f a p p e a l

You may appeal against this decision in compliance with provisions of Section 81 et seq. of Act No. 500/2004 Sb., the Rules of Administrative Procedure, as amended, to the State Institute for Drug Control within 15 days following its delivery. The Ministry of Health of the Czech Republic decides on the appeal.

official stamp

PharmDr. Ivan Buzek
Head of Department of Pharmacy and Distribution

Annex No. 1 – The scope of the drug distribution authorisation (1 page)

Annex No. 1/1 to Decision File No. sukls92265/2024 dated 10 June 2024

THE SCOPE OF DRUG DISTRIBUTION AUTHORISATION

The name and address of the distribution point: arex PHARMA s.r.o., K sokolovně 218, 104 00 Prague 10 – Uhříněves

1. **MEDICINAL PRODUCTS**

1.1 ☒ with marketing authorisation in the country/countries of the EEA

1.2 ☒ without marketing authorisation in the EEA and designated for the EEA's market *

1.3 ☒ without marketing authorisation in the EEA and designated for export

2. **AUTHORISED DISTRIBUTION ACTIVITIES**

2.1 ☒ Purchase/Procurement

2.2 ☒ Storage

2.3 ☒ Delivery

2.4 ☒ Export

2.5 ☐ Other activities: —

3. **MEDICINAL PRODUCTS WITH ADDITIONAL REQUIREMENTS**

3.1 ☒ Products in accordance with Art. 83 of Directive 2001/83/EC[1]

3.1.1 ☒ Medicinal products derived from blood

3.1.2 ☒ Immunological medicinal products

3.1.3 ☐ Radiopharmaceuticals (including radionuclide kits)

3.2 ☐ Medicinal gases

3.3 ☒ Cold chain products (requiring manipulation in low temperatures)

3.4 ☐ Other products: —

All restrictions and explanatory notes and specifications of conditions regarding the scope of distribution: ---

*Art. 5 of Directive 2001/83/EC or No. 83 of Regulation EC/726/2004

official stamp

PharmDr. Ivan Buzek
Head of Department of Pharmacy and Distribution

1 Apart from this authorisation, the authorisation to handle medicinal products containing narcotic and psychotropic substances is required for their distribution. It is issued by the Ministry of Health of the Czech Republic in accordance with Act No. 167/1998 Sb., on addictive substances and on amendment to some other laws, as amended

PŘEKLADATELSKÁ DOLOŽKA

Já, Mgr. Ivana Nezbedová, IČ: 71902341, soudní překladatelka jazyka českého, slovenského a anglického zapsaná v seznamu tlumočníků a překladatelů vedeném Ministerstvem spravedlnosti České republiky, tímto stvrzuji, že jsem osobně provedla překlad připojené listiny, a že tento překlad souhlasí s textem předmětné listiny. Při provádění překladu nebyl přibrán konzultant.

Tento úkon je zapsán v evidenci úkonů vedené Ministerstvem spravedlnosti České republiky pod číslem: **143507/2024**….

Tento překladatelský úkon byl proveden v elektronické podobě v souladu s ust. § 27 zákona č. 354/2019 Sb., o soudních tlumočnících a soudních překladatelích v platném znění, ust. § 27 odst. 2, resp. 3 a § 38 vyhl. č. 506/2020 Sb., o výkonu tlumočnické a překladatelské činnosti v platném znění, přičemž překládaná písemnost v elektronické podobě je nedílnou součástí tohoto překladatelského úkonu.

V Táboře / Tábor, 24. 06. 2024

TRANSLATOR´S CLAUSE

I, Mgr. Ivana Nezbedová, Registration Number: 71902341, a certified translator of the Czech, Slovak and English language, entered in the List of Interpreters and Translators maintained by the Ministry of Justice of the Czech Republic, I confirm I have translated the attached document by myself and this translation corresponds with the text of the relevant document. No consultant was taken on.

This act is recorded in the register of translation acts maintained by the Ministry of Justice of the Czech Republic under no.: **143507/2024**……..

This act was carried out in the electronic form pursuant to Section 27 of Act No. 354/2019 Sb., the Certified Interpreters and Certified Translators Act, as amended, Section 27(2, 3) and Section 38 of Regulation No. 506/2020 Sb., concerning the profession of translators and interpreters, as amended, the translated document in the electronic format being an integral part of this act.

Mgr. Ivana Nezbedová
překladatelka/translator

Mgr. Ivana Nezbedová

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